NATIONAL INSTITUTES OF HEALTH

FISCAL YEAR 2004

PLAN FOR HIV-RELATED RESEARCH

IX: RACIAL AND ETHNIC MINORITIES

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

OFFICE OF AIDS RESEARCH

AREA OF EMPHASIS:

Racial and Ethnic Minorities

SCIENTIFIC ISSUES

More than two decades of research have yielded new understanding of the natural history and pathogenesis of HIV infection, as well as insights into the human immune system. Treatment options have broadened, yielding increased survival for those living with HIV infection. Prevention has been shown to be effective, particularly when delivered in a manner that is not only culturally sensitive, but also contextually appropriate. Yet, despite these scientific achievements, the benefits of these findings have not been realized consistently across all affected population groups.

HIV infection, like many other disease states, reflects the ongoing health disparity among racial and ethnic minority communities. Despite prevention efforts, HIV seroprevalence in racial and ethnic minority communities is disproportionately higher than in majority and mainstream communities. Indeed, in many urban centers, there are pockets of HIV seroprevalence that mimic the developing world. These findings, in conjunction with the resurgence of sexually transmitted infections and associated high-risk behaviors, demonstrate the need for comprehensive strategies to decrease not only HIV transmission in affected vulnerable populations, but also for continued improvements in treatment options and treatment outcomes.

The interplay of cultural, economic, political, individual, and societal factors in general, especially within racial and ethnic minority communities, requires comprehensive as well as innovative interventions. These interventions must go beyond an emphasis upon the training of minority scientists (which

remains a pressing and unmet need) and include attention to the development of dedicated programs to develop and support research infrastructure and organizational capacity within minority-serving institutions. Similar initiatives have already been launched in the international setting (e.g., the Comprehensive International Program of Research on AIDS), where the challenges and barriers are similar. The demographics of the epidemic, in stark contrast to the demographics of extramural and intramural NIH investigators, continue to demonstrate a widening divide between those infected and those conducting research upon the infected. Failure to address this growing divide will impact current and future NIH-sponsored HIV-related research.

OBJECTIVE:

- **Increase the number of NIH-funded minority investigators to increase their critical mass.**

The approach to this ongoing challenge must be multifaceted with broad-based support across all NIH Institutes and Centers. The focus, in addition to building research capacity and infrastructure within minority institutions, cannot overlook the importance of community-research partnerships. These partnerships provide an important opportunity for bidirectional information transfer, as well as the development of a research agenda of importance to both the affected communities and the investigators. Included within this research agenda would be increased collaboration across Department of Health and Human Services (DHHS) agencies with significant HIV/AIDS initiatives.

OBJECTIVE:

- **Increase the capacity for multidisciplinary HIV/AIDS research in minority institutions and minority communities through a *sustained* and developmentally staged program.**

However, increased attention upon minority investigators and minority institutions is insufficient to bridge the gap between the scientific community and the communities most affected by HIV infection. Within these communities, the main routes of HIV infection—unprotected sexual intercourse and substance abuse—are inextricably linked to a range of underlying community and societal factors, as well as community norms and cultures. Cultural competency, or the ability to see the world through the lens of a particular culture, not just cultural awareness, is a critical skill in understanding the context of the epidemic in racial and ethnic minority communities. In addition to understanding the cultural context of HIV transmission, these skills must be translated into clinical research designs

that will produce outcomes that have "real world" relevance for affected communities. Incorporating the needs and perspectives of racial and ethnic minority communities into all aspects of HIV clinical research, from trial design to dissemination of study results, is central to the establishment and maintenance of a sustained increase in minority participation in NIH-sponsored HIV-related research.

Participation of racial and ethnic minority communities in clinical research is essential, to further not only our understanding of treatment of HIV infection, but also to better identify the impact of race and ethnicity upon treatment side effects, including the impact of genetics and pharmacogenetics upon HIV therapy in this population. Identification of specific proteins, such as p-glycoproteins, suggests that much remains to be learned about the complex interplay of host genetics, HIV infection, and treatment upon the course of HIV disease progression. Higher rates of co-morbid diseases in racial and ethnic minority communities, such as hepatitis C, provide additional opportunities to determine the effect of these co-infections not only upon HIV infection, but also upon treatment options for HIV infection, or the sequelae of treatment, such as metabolic abnormalities. To achieve this objective, recruitment and retention strategies for clinical studies must be appropriate for the target population. The current limited partnerships between NIH-funded research institutions and community-based institutions (including community-based organizations) limit opportunities for unique collaborations and greater community participation. Ongoing evaluation of existing NIH research-community partnerships is needed. How these existing partnerships compare to successful community research models will delineate what is needed to address the significant scientific challenges that confront racial and ethnic minority communities. The development and maintenance of balanced partnerships, in conjunction with a sustained staged effort to develop research as well as infrastructure, offer the greatest chance for lasting gains in this area. Interventions that are effective, but not sustainable, represent a zero sum gain for the participating communities.

OBJECTIVE:

- **Increase funded research on the causes of health disparities in HIV/AIDS and effective interventions to reduce these disparities.**

Gains have been made in the recruitment and retention of racial and ethnic minorities in clinical research trials. Given the continued increase in the transmission of HIV infection among racial and ethnic minorities, superimposed upon a foundation of co-morbid diseases and health disparities, the need for new and innovative approaches for increased

minority representation in both the subject and investigator populations is clear. In addition to the existing recruiting mechanisms, new approaches to outreach, as well as information dissemination about AIDS clinical trials, must continue to expand. Increased support to develop and disseminate Internet-based research resources for community-based organizations, as well as those that provide front line service and case management in racial and ethnic minority communities, is essential. Additional focus upon community preparedness to participate in not only vaccine trials but also treatment trials is needed. The long history of mistrust of the medical research community within racial and ethnic minority communities will not be erased by two decades of HIV research. These communities have not seen research questions that reflected their interests, nor have those who conducted that research resembled members of the affected community. No single approach will immediately eliminate the many gaps in the community HIV knowledge of the prevention, treatment, and vaccine research questions that confront the current HIV research agenda. Hence, a multifaceted approach that increases the HIV knowledge base, that provides information to community-based organizations and providers, that trains community members to participate on community advisory boards, and that allows for bidirectional information exchange between researchers and community members is one that will encourage minority participation at all levels. Minority communities will continue to decline research participation or cooperation until there is greater collaboration between the community and the scientific community, with attention to the sustainability of the intervention before *any* trial is begun.

OBJECTIVE:

- **Include racial and ethnic minorities in prevention, therapeutic, and vaccine clinical trials in numbers that reflect the current epidemic trends and that address the research questions relevant to racial and ethnic minorities.**

As noted earlier, HIV transmission domestically continues to disproportionately impact racial and ethnic minorities. Driven by poverty, drug use, and many other social ills, the transmission of HIV infection in these communities is only further complicated by the barriers to the provision of care and treatment. Barriers to accessing care (as well as clinical trials) are widespread within these communities and may occur at many levels—individual, community, and institutional. Some of these barriers may be geographic, as centers for HIV care and research are not evenly distributed in the United States, especially in those areas where the epidemic is exploding (e.g., rural and southern populations). A continued

emphasis on studies that identify those factors that promote and impede early access to care, treatment, and clinical trials is important to determine effective interventions. The identification and study of these effective interventions to reduce or eliminate these barriers will be a fundamental step toward closing the gap between racial and ethnic minorities and whites. However, identification alone will be insufficient, as sustaining the interventions that have proven effective will be necessary to ensure ongoing attention to these challenges.

OBJECTIVE:

- **Develop, pilot, and evaluate effective interventions to prevent and reduce HIV transmission and its co-morbidities, as well as HIV-related health disparities in racial and ethnic minorities.**

Effective, sustainable prevention messages are desperately needed in these communities, as well as an understanding of the impact of those factors that may interfere with prevention messages. To better understand the impact of these factors, basic behavioral research is needed to effectively target the many subpopulations within racial and ethnic minority communities, including those who use illicit substances and those with multiple diagnoses (e.g., mental disorders and alcohol/drug abuse). Reduction or elimination of language barriers that limit participation in prevention research is also needed in communities where English is not the primary language. Any standardized scales to be used in these studies should have been validated in minority populations, especially given the cultural contexts within which risk behavior occurs. The role of the family and caregivers in HIV prevention in racial and ethnic minority communities needs to be explored. Increased awareness of NIH HIV prevention activities is needed at the community level, which can be achieved through closer collaboration between NIH and all other DHHS agencies charged with decreasing HIV transmission through public education. Such collaborations should include, but not be limited to, information dissemination and translation of research findings. These activities also need to include technology transfer of effective prevention programs to community-based organizations that reach at-risk groups among racial and ethnic minorities.

OBJECTIVE:

- **Increase information dissemination and technology transfer to racial and ethnic minority communities and community-based organizations, with the explicit goal of increasing their capacity to utilize HIV-related research in meeting their specific needs.**

Given the current state of the epidemic in racial and ethnic minority communities, even the most effective prevention interventions alone will not meet the needs of the millions already infected with HIV. Effective drug treatment regimens identified in the controlled environment of a clinical trial do not perform as well in urban, inner-city HIV clinics. Poor adherence is the major reason for this finding and is a reflection of a host of underlying economic, individual, and social factors. There is a need for the study of multilevel interventions, including the individual, peer, family, and community levels. Further studies of the impact of noncompliance in racial and ethnic minorities upon the emergence of drug-resistant HIV, multidrug-resistant tuberculosis, and disease progression are needed.

OBJECTIVE:

- **Study those approaches to treatment and adherence that impact health outcomes in racial and ethnic minority communities.**

Increased support is recommended for basic science studies of the racial and ethnic differences in body composition and pharmacokinetics, and their potential role in suboptimal drug effects. The impact of drug side effects and cosmetic changes and their role in noncompliance also warrants further study, especially in racial and ethnic minority communities, where such changes can unmask underlying HIV infection. Finally, the development of culturally appropriate and population-specific models of treatment acceptance and adherence is needed.

SCIENTIFIC OBJECTIVES AND STRATEGIES

OBJECTIVE - A:

Increase the capacity for multidisciplinary HIV/AIDS research in minority institutions and minority communities through a *sustained* and developmentally staged program.

STRATEGIES:

- Increase the investment, through expanded funding allocated for research infrastructure development at minority institutions, to increase their capacity to support HIV/AIDS research through a trans-NIH program solely dedicated to this purpose.
- Provide ongoing infrastructure support to develop and improve basic science capacity at minority-predominant and minority-serving institutions.
- Provide additional infrastructure support, based upon a needs assessment of the minority institution, including but not limited to visiting scholars, technical assistance for grants and contract development and management, and electronic and telecommunications capacity building.
- Provide long-term support for the planning and implementation of a comprehensive HIV/AIDS research agenda culminating in independent, self-sustaining research at minority institutions.
- Develop culturally appropriate and relevant training models to address the needs of the research and support personnel necessary for the conduct of ongoing research at minority institutions.
- Fund planning and organizational grants targeting minority institutions and communities. Emphasis should be placed upon grants that develop academic-community partnerships.
- Ensure adequate resources for the development of equal and productive partnerships between minority and majority institutions, and community-based organizations, with the funds located at the minority applicant institution.

OBJECTIVE - B:

Increase the number of NIH-funded minority investigators to increase their critical mass.

STRATEGIES:

- Create alternative funding mechanisms including, but not limited to, career development and training programs at Centers of Excellence. Utilize special emphasis panels to provide funds for minority investigators.
- Increase minority institutions and minority investigators awareness of *existing* grant mechanisms to support the transition from trainee to independent investigator. Conduct a review of the effectiveness of these existing grant mechanisms.
- Enhance the tracking and reporting of existing training workshops and training awards that support the transition from trainee to independent investigator to better determine the effectiveness of these interventions.
- Increase the number of minority reviewers on study sections as well as on special emphasis panels.
- Establish a scholarship program to enable minority investigators to attend scientific meetings.
- Develop strategies to recruit trainees and mentors at all levels, including meeting scholarships, designed to enable continued participation and retention in the mentor-trainee relationship. Additional strategies could include economic and in-kind support.

OBJECTIVE - C:

Increase funded research on the causes of health disparities in HIV/AIDS and effective interventions to reduce these disparities.

STRATEGIES:

- Identify and study the effectiveness of various strategies to reduce or eliminate health disparities at the individual, institutional, and community levels.
  - Study the factors that promote and/or impede early access to care and treatment.
  - Study the effectiveness of culturally appropriate interventions for primary and secondary prevention.
- Study the combined effect of several factors that disproportionately impact racial and ethnic minorities, such as racism, poverty, homophobia, and homelessness, in creating the health disparities observed at the individual and community levels.
  - Study the impact of these effects upon individual and community behavior. Determine the significance of this impact in HIV infection among racial and ethnic minorities.
  - Continue the study of the biology of HIV infection among racial and ethnic minorities, including: vulnerability to HIV infection, vulnerability to opportunistic infection, HIV transmission, disease progression, and the development of drug resistance.
- Encourage, through specific funding announcements, basic and clinical research to elucidate the influence of cultural, economic, biological, behavioral, gender, and age factors upon the health disparities in HIV/AIDS among racial and ethnic minorities.
  - Design clinical trials with sufficient power to detect racial, ethnic, and gender differences.
  - Continue to explore racial, ethnic, gender, and age-associated differences in the immune response to HIV infection and its sequelae.
- Conduct research on the interactions between economic and education disparities among racial and ethnic minorities on health outcomes in HIV infection.

- Study the impact of other co-morbid diseases, including but not limited to the hepatitides, tuberculosis, mental illness, diabetes, substance abuse, sexually transmitted infections, and their management upon health outcomes in racial and ethnic minorities, including morbidity and mortality.
- Examine the effects of HIV infection upon the physiologic, immunologic, hormonal, and neuropsychological development of adolescents.

OBJECTIVE - D:

Include racial and ethnic minorities in prevention, therapeutic, and vaccine clinical trials in numbers that reflect the current epidemic trends and that address the research questions relevant to racial and ethnic minorities.

STRATEGIES:

- Develop clinical trial study designs that examine prospectively the racial/ethnic/gender differences in transmission, pathophysiology, and treatment outcomes.
- Encourage the use of ClinicalTrials.gov and the AIDS Clinical Trials Information Services (ACTIS) as tools to inform and promote an understanding of the clinical trials process and of current clinical trials in minority populations.
- Conduct HIV clinical trials in racial and ethnic minorities that explore differential responses to treatment, metabolic toxicities, immune responses to HIV infection, and other research questions of interest to these communities.
- Promote interagency research to identify the impact of criminal justice, economic, educational, and health care disparities, as well as public policy factors that increase and sustain the disparities in health outcomes among racial and ethnic minorities.

OBJECTIVE - E:

Develop, pilot, and evaluate effective interventions to prevent and reduce HIV transmission and its co-morbidities, as well as HIV-related health disparities.

STRATEGIES:

- Expand research to identify specific mechanisms of transmission, and the critical factors that influence transmission among racial and ethnic minorities.
  - Fund research to explore the impact of antiretroviral therapy upon transmission in general, and specifically the transmission of drug-resistant HIV infection in racial and ethnic minority communities.
  - Support research on the potential impact of vaccines and microbicides upon HIV transmission among racial and ethnic minorities.
- Increase community-level awareness of HIV prevention through closer collaboration between NIH and all other DHHS agencies, as well as a trans-NIH strategy for information dissemination to racial and ethnic minority communities.
- Develop and support innovative models to conduct outcomes research in racial and ethnic minority communities.
- Support research that explores the role of the family, caregivers, and nontraditional organizations in the prevention of HIV transmission in racial and ethnic minority communities.

OBJECTIVE - F:

Study those approaches to treatment and adherence that impact health outcomes in racial and ethnic minority communities.

STRATEGIES:

- Study the short- and long-term effects of nonadherence in racial and ethnic minorities, including but not limited to the emergence of drug-resistant HIV infection, multidrug-resistant tuberculosis, opportunistic infections, and disease progression.
- Study racial and ethnic differences in adherence, and the gender-related differences associated with chronic nonadherence.
- Study the effects of multilevel interventions (individual, peer, family, community, faith-based) upon adherence.
- Study the role of complementary therapies upon treatment for HIV infection and its complications.
- Define the role and impact of health beliefs upon treatment acceptance and adherence in racial and ethnic minorities.
- Enhance the development of novel therapeutic regimens for HIV and the associated co-infections, including the use of genomics.

OBJECTIVE - G:

Increase information dissemination and technology transfer to racial and ethnic minority communities and community-based organizations, with the explicit goal of increasing their capacity to utilize HIV-related research in meeting their specific needs.

STRATEGIES:

- Fund information and technology transfer of effective prevention interventions to racial and ethnic minority community-based organizations and providers of care.
- Support technology transfer of culturally and contextually appropriate prevention programs to community-based organizations that reach at-risk groups among racial and ethnic minorities.
- Review and assess the effectiveness of current programs designed to disseminate information and transfer technology to racial and ethnic minority communities.
- Establish specific mechanisms for community consultation at all phases of research development, implementation, and dissemination of results.
- Establish mechanisms for sharing study outcomes with the affected community.
- Establish mechanisms for principal investigator-community collaborations designed to identify resources, including infrastructural, to sustain successful prevention interventions.

APPENDIX A:

NIH Institutes and Centers

NIH INSTITUTES AND CENTERS

NCI	National Cancer Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NINDS	National Institute of Neurological Disorders and Stroke
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
CC	Warren Grant Magnuson Clinical Center
CIT	Center for Information Technology
NCCAM	National Center for Complementary and Alternative Medicine
NCRR	National Center for Research Resources
FIC	Fogarty International Center
CSR	Center for Scientific Review
NCMHD	National Center on Minority Health and Health Disparities
NIBIB	National Institute of Biomedical Imaging and Bioengineering

APPENDIX B:

FY 2004 OAR Planning Group for Research Related to Racial and Ethnic Minorities

FY 2004 RACIAL AND ETHNIC MINORITIES PLANNING GROUP

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APPENDIX C:

List of Acronyms

LIST OF ACRONYMS

ART	antiretroviral therapy
ARV	antiretroviral
ACTIS	AIDS Clinical Trials Information Service
AIDS	acquired immunodeficiency syndrome
AITRP	AIDS International Training and Research Program, FIC
ATI	Analytic Treatment Interruption
ATIS	HIV/AIDS Treatment Information Service
BSL	biosafety level
B/START	Behavioral Science Track Award for Rapid Transition
CAB	community advisory board
CAPS	Center for AIDS Prevention Studies (University of California, San Francisco)
CBO	community-based organization
CDC	Centers for Disease Control and Prevention
CFAR	Center for AIDS Research
CIPRA	Comprehensive International Programs for Research on AIDS
CMS	Centers for Medicare and Medicaid Services
CMV	cytomegalovirus
CNS	central nervous system
CSF	cerebrospinal fluid
CTL	cytotoxic T lymphocyte
DC	dendritic cell
ddI	dideoxyinosine
DHHS	Department of Health and Human Services
DNA	deoxyribonucleic acid
EBV	Epstein-Barr virus
FDA	Food and Drug Administration
FIRCA	Fogarty International Research Collaboration Award, FIC
GBV-C	GB virus (hepatitis G)

GCP	Good Clinical Practices
GCRC	General Clinical Research Center
GFATM	Global Fund for AIDS, Tuberculosis, and Malaria
GI	gastrointestinal
GLP/GMP	good laboratory practice/good manufacturing practice
HAART	highly active antiretroviral therapy
HBCU	Historically Black Colleges and Universities
HBV	hepatitis B virus
HCV	hepatitis C virus
HERS	HIV Epidemiology Research Study
HHV	human herpesvirus
HIV	human immunodeficiency virus
HPTN	HIV Prevention Trial Network
HPV	human papillomavirus
HRSA	Health Resources and Services Administration
HVTN	HIV Vaccine Trials Network
IC	Institute and Center
ICC	invasive cervical cancer
IDU	injecting drug user
IRB	institutional review board
IUD	intrauterine device
JCV	JC virus
KS	Kaposi's sarcoma
KSHV	Kaposi's sarcoma herpesvirus
LRP	Loan Repayment Program, NIH
MAC	*Mycobacterium avium* complex
MDR-TB	multidrug-resistant tuberculosis
MHC	major histocompatibility complex
MSM	men who have sex with men
MTCT	mother-to-child transmission

N9	nonoxynol
NAFEO	National Association for Equal Opportunity in Higher Education
NGO	nongovernment organization
NHL	non-Hodgkin's lymphoma
NHP	nonhuman primate
NIH	National Institutes of Health
NMAC	National Minority AIDS Council
NRTIs	nucleoside reverse transcriptase inhibitors
OAR	Office of AIDS Research, NIH
OARAC	Office of AIDS Research Advisory Council
OD	Office of the Director, NIH
OI	opportunistic infection
OPHS	Office of Public Health and Science
PBMC	peripheral blood mononuclear cell
PCP	*pneumocystis carinii* pneumonia
PML	progressive multifocal leukoencephalopathy
RCMI	Research Center in Minority Institution
RCT	randomized clinical trial
RFIP	Research Facilities Infrastructure Program
RNA	ribonucleic acid
RPRC	Regional Primate Research Center
SAMHSA	Substance Abuse and Mental Health Services Administration
SCID	severe combined immunodeficiency
SHIV	chimeric simian/human immunodeficiency virus
SIT	scheduled intermittent therapy
SIV	simian immunodeficiency virus
SPF	specific pathogen-free
STD	sexually transmitted disease
STI	structured treatment interruption; sexually transmitted infection
TB	tuberculosis

Th	T helper cells
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
VEE	Venezuelan equine encephalitis virus
VRC	Vaccine Research Center
WHO	World Health Organization
WIHS	Women's Interagency HIV Study
WITS	Women and Infants Transmission Study
WRAIR	Walter Reed Army Institute for Research